



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Transfer of Ownership and Exclusive Use of 510(K) Number K113336 for the CDC DENV-1-4 REAL-TIME RT-PCR ASSAY

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice that the Centers for Disease Control and Prevention, Department of Health and Human Services, is contemplating the transfer of ownership and exclusive use of 510(k) Number K113336 to American Type Culture Collection (ATCC), a District of Columbia non-profit corporation. 510(k) Number K113336 allows marketing of the CDC DENV-1-4 Real-Time RT-PCR Assay, an *in vitro* molecular diagnostic test that consists of a panel of oligonucleotide primers and dual-labeled hydrolysis (TaqMan®) probes for the qualitative detection of dengue virus target sequences in serum and plasma using nucleic acid isolation, amplification, and detection on the ABI 7500 Fast Dx Real-Time PCR instrument. The contemplated transfer would occur in conjunction with the grant of a non-exclusive patent license to ATCC to practice the inventions embodied in patent applications under HHS Ref. No E-148-2013/0, including U.S. Provisional Patent Application No. 61/554,126, entitled “Broad Detection of Dengue Virus Serotypes”, filed November 1, 2011.

DATES: Only written comments and/or applications for a license to practice the inventions embodied in HHS Ref. No E-148-2013/0 that include a request for the transfer of 510(k) Number

K113336 that are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESSES: Any inquiries, comments, or other materials relating to the contemplated 510(k) transfer should be directed to: Tara L. Kirby, Ph.D., Unit Chief, CDC Unit, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4426; Facsimile: (301) 402-0220; E-mail: tarak@mail.nih.gov. Requests for copies of CDC's patent applications related to "Broad Detection of Dengue Virus Serotypes" (HHS Ref. No. E-148-2013/0), which are available for non-exclusive licensing, should also be directed as above.

SUPPLEMENTARY INFORMATION: Complete applications for a license to practice the inventions embodied in HHS Ref. No E-148-2013/0 that include a request for the transfer of 510(k) Number K113336 filed in response to this notice will be treated as objections to the grant of the contemplated transfer. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 28, 2014.

Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health.

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